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PATENT

Appl. No. 10/621,254
Amdt. dated February 5, 2007
Reply to Office Action of January 4, 2007

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Currently amended) A method comprising:
administering, to a subject, a composition ~~according to claim 31~~, comprising at least one ligand for a pattern recognition receptor ~~molecule family of receptors~~ and a delivery vehicle; and exposing said subject to radiation to a subject.
2. (Original) The method of claim 1, wherein a ligand for a pattern recognition receptor comprises a ligand for a signaling pattern recognition receptor.
3. (Previously presented) The method of claim 2, wherein said signaling pattern recognition receptor comprises at least one receptor selected from Toll-like receptors TLR-1, TLR-2, TLR-3, TLR-4, TLR-5, TLR-6, TLR-7, TLR-8, TLR-9, TLR-10, TLR-11 and TLR-12, and mannan-binding lectins, and macrophage mannose receptor and scavenger receptors.
4. (Original) The method of claim 3, wherein said ligand comprises a ligand for TLR-2, TLR-3 and/or TLR-9.
5. (Original) The method of claim 1, wherein a ligand for a pattern recognition receptor comprises a ligand for an endocytic pattern recognition receptor or scavenger receptor or mannose-binding receptor.
6. (Original) The method of claim 1, further comprising modulating an immune response in said subject.
7. (Original) The method of claim 6, wherein modulating an immune response comprises augmenting an immune response.

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8. (Original) The method of claim 6, wherein modulating an immune response comprises down regulating an immune response.

9. (Original) The method of claim 6, wherein modulating an immune response comprises augmenting an immune response in a subject disposed of cancer.

10. (Previously presented) The method of claim 9, wherein cancer comprises one or more selected from lung cancer, skin cancer, liver cancer, bone marrow cancer, leukemia, ovarian cancer, breast cancer, prostate cancer, colon cancer, lymphoma, brain cancer, renal cell cancer, and cancers of mesenchymal tissues.

11-18. (Canceled)

19. (Original) The method of claim 6, wherein modulating an immune response comprises modulating an immune response in a subject disposed of a disease due to abnormal production of proteins in the body.

20-30. (Canceled)

31. (Currently amended) The method of claim 1 wherein said [[A]] composition comprises comprising:

a ligand for the pattern recognition molecule family of receptors; and
a delivery vehicle wherein said ligand is complexed to or within the delivery vehicle and said composition is capable of inducing an immune response in a subject.

32. (Currently amended) The ~~composition~~ method of claim 31, wherein inducing an immune response comprises inducing an innate immune response.

33. (Currently amended) The ~~composition~~ method of claim 32, wherein the innate immune response comprises an innate immune response by macrophages, neutrophils, NK cells, and/or dendritic cells.

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34. (Currently amended) The ~~composition~~ method of claim 31,
wherein the delivery vehicle comprises a liposome.

35. (Currently amended) The ~~composition~~ method of claim 34,
wherein the ratio of liposome to ligand comprises about 1:1 to about 100:1mmol liposome to mg
ligand.

36. (Currently amended) The ~~composition~~ method of claim 34,
wherein said ratio of liposomes to ligand is about 16:1 or about 8:1mmol liposome to mg ligand.

37. (Currently amended) The ~~composition~~ method of claim 34,
wherein said liposome comprises at least one liposome selected from a positively charged
liposome; a negatively charged liposome; and a neutral liposome.

38. (Currently amended) The ~~composition~~ method of claim 31,
wherein said delivery vehicle comprises any combination of liposomes.

39. (Currently amended) The ~~composition~~ method of claim 37,
wherein said positively charged liposome is complexed to a ligand for the pattern recognition
molecule family of receptors.

40. (Currently amended) The ~~composition~~ method of claim 34,
wherein said liposome consists of a mixture of charged and neutral lipids of DOTIM (1-(2-
(oleoyloxy)ethyl)-2-oleyl-3-(2-hydroxyethyl)imidazolinium) and cholesterol in a 1:1 molar ratio.

41. (Currently amended) The ~~composition~~ method of claim 31,
wherein the delivery vehicle is non-liposomal.

42. (Currently amended) The ~~composition~~ method of claim 41, wherein the
non-liposomal delivery vehicle comprises at least one vehicle selected from polypeptides,
polyamines, chitosan, PEI, polyglutamic acid, protamine sulfate, and microspheres.

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43. (Currently amended) The ~~composition~~ method of claim 34,
wherein said ligand comprises a TLR ligand.

44. (Currently amended) The ~~composition~~ method of claim 43,
wherein the TLR ligand comprises a nucleic acid molecule ~~any portion of a bacterium~~.

45. (Currently amended) The ~~composition~~ method of claim 44,
wherein said nucleic acid molecule is from ~~any portion of a bacterium further comprises any
portion of a bacterium that associates with a TLR.~~

46. (Canceled)

47. (Currently amended) The ~~composition~~ method of claim 43,
wherein the TLR ligand comprises a nucleic acid molecule from ~~any portion of a fungal
organism.~~

48-49. (Canceled)

50. (Currently amended) The ~~composition~~ method of claim 43,
wherein the TLR ligand comprises a nucleic acid molecule from ~~any portion of a multicellular
organism.~~

51. (Currently amended) The ~~composition~~ method of claim 43,
wherein the TLR ligand comprises a nucleic acid molecule from ~~any portion of a unicellular
organism.~~

52. (Currently amended) The ~~composition~~ method of claim 31, wherein said
ligand comprises at least one of a glycoprotein, lipoprotein, glycolipid, carbohydrate, lipid,
nucleic acid and/or protein or peptide sequence derived from any portion of a bacterial pathogen.

53-54. (Canceled)

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55. (Currently amended) The ~~composition~~ method of claim 31, wherein said ligand comprises a glycoprotein, lipoprotein, glycolipid, carbohydrate, lipid, nucleic acid and/or protein or peptide sequence derived from any portion of a fungal organism.

56. (Currently amended) The ~~composition~~ method of claim 31, wherein the ligand comprises a glycoprotein, lipoprotein, glycolipid, carbohydrate, lipid, nucleic acid and and/or protein or peptide sequence derived from any portion of a viral organism.

57. (Currently amended) The ~~composition~~ method of claim 31, wherein the ligand comprises a glycoprotein, lipoprotein, glycolipid, carbohydrate, lipid, nucleic acid and and/or protein or peptide sequence derived from any portion of a rickettsial organism.

58. (Currently amended) The ~~composition~~ method of claim 31, wherein the ligand comprises a glycoprotein, lipoprotein, glycolipid, carbohydrate, lipid, nucleic acid and and/or protein or peptide sequence derived from any portion of a parasitic organism.

59. (Currently amended) The ~~composition~~ method of claim 31, wherein the ligand comprises a glycoprotein, lipoprotein, glycolipid, carbohydrate, lipid, nucleic acid and and/or protein or peptide sequence derived from any portion of an arthropod organism.

60. (Currently amended) The ~~composition~~ method of claim 31, wherein said ligand comprises a nucleic acid encoding a TLR ligand.

61. (Currently amended) The ~~composition~~ method of claim 60, wherein said nucleic acid comprises at least one molecule selected from bacterial DNA, eukaryotic DNA, dsDNA, ssDNA a synthetic oligonucleotide, RNA, and synthetic RNA.

62. (Currently amended) The ~~composition~~ method of claim 61, wherein said oligonucleotide comprises at least one of poly I:C or related poly I:C oligonucleotides.

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63. (Currently amended) The ~~composition~~ method of claim 31, wherein said ligand is a mixture of two or more different TLR ligands in ratios sufficient for eliciting an immune response.

64. (Currently amended) The ~~composition~~ method of claim 31, wherein said ligand consists of any molecule that associates with and/or stimulates a pattern recognition receptor.

65. (Currently amended) The ~~composition~~ method of claim 31, wherein said ligand comprises a synthetically generated ligand that binds to and stimulates a pattern recognition receptor.

66. (Currently amended) The ~~composition~~ method of claim 31, further comprising a molecule with a steroid backbone.

67. (Currently amended) The ~~composition~~ method of claim 60, further comprising a DNA condensing agent.

68. (Currently amended) The ~~composition~~ method of claim 67, wherein the DNA condensing agent is polyethylenimine (PEI).

69-84. (Canceled)

85. (Currently amended) The method of claim 1, wherein said ~~administering comprises delivery~~ claim 83, further comprising administering said composition by a route selected from intravenously, intraperitoneally, by inhalation, subcutaneously, intradermally, intranodally, intramuscularly, intranasally, orally, rectally, intravaginally, intravesicularly, intraocularly, and topically.

86. (Currently amended) The method of claim 1 ~~claim 83~~, further comprising augmenting an immune response in a subject disposed of cancer.

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87. (Previously presented) The method of claim 86, wherein the cancer comprises at least one cancer selected from of lung cancer, skin cancer, liver cancer, bone marrow cancer, ovarian cancer, breast cancer, prostate cancer, colon cancer, lymphoma, brain cancer, renal cell cancer, and cancers of mesenchymal tissues.

88-111. (Canceled)

112. (Currently amended) A method of treating a subject with cancer comprising:
administering a composition ~~according to claim 31~~, comprising at least one ligand for a pattern recognition receptor and a delivery vehicle, in conjunction with radiation at least ~~one cancer~~ therapy wherein said method elicits a response in a subject disposed of cancer.

113. (Currently amended) The method of claim 112, further comprising wherein said cancer therapy comprises at least one therapy consisting of hyperthermia therapy, ~~radiation therapy~~, chemotherapy, photodynamic therapy (PDT), surgery, ultrasound, and focused ultrasound.

114. (Original) The method of claim 112, wherein the order of administering the therapy generates different responses.

115. (Original) The method of claim 114, wherein radiation therapy is introduced first.

116. (Original) The method of claim 114, wherein radiation therapy is introduced last.

117. (Original) The method of claim 114, wherein radiation therapy is introduced concurrently.

118. (Original) The method of claim 112, wherein the pattern recognition receptor ligand comprises a nucleic acid molecule.

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119. (Original) The method of claim 112, wherein the pattern recognition receptor ligand comprises bacterial DNA.

120. (Original) The method of claim 112, wherein the delivery vehicle comprises a liposome.

121. (Original) The method of claim 112, wherein the delivery vehicle comprises a non-liposomal delivery vehicle.

122-150. (Canceled)

151. (New) The method of claim 1, wherein a ligand for a pattern recognition molecule receptor comprises a ligand for an pattern recognition receptor.

152. (New) The method of claim 1, wherein the order of administering the therapy generates different responses.

153. (New) The method of claim 152, wherein radiation exposure occurs first.

154. (New) The method of claim 152, wherein radiation exposure occurs last.

155. (New) The method of claim 152, wherein radiation exposure is concurrent with said administering.

156. (New) The method of claim 1, wherein the ligand comprises a synthetic compound capable of binding a pattern recognition receptor.

157. (New) The method of claim 156, wherein the synthetic compound comprises immadazoquinoline.